APR 0 1 2014

510(k) SUMMARY
Stryker Imbibe Needle

February 18th, 2014

510(k) Number (if known): K140414

1. **Contact Person**

John Urtz
Senior Regulatory Affairs Specialist
(e-mail) john.urtz@stryker.com

Orthovita, Inc.
77 Great Valley Parkway
Malvern, PA 19355
(t) 610-407-7450 – (f) 484-323-8803

2. **Device Name and Classification**

Product Name:	Imbibe Needle
Classification Name:	Instrument, Biopsy Orthopedic Manual Surgical Instrument
Common or Usual Name:	Gastroenterology-urology biopsy instrument
Regulation Number:	876.1075 888.4540
Reviewing Panel:	Gastroenterology/Urology Surgical, Orthopedic, and Restorative Devices
Device Class:	Class II
Product Code:	KNW LXH

3. **Predicate Device(s)**

Orthovita Inc.'s Imbibe Needle (K050795)

4. **Device Description**

The Imbibe Needle is a manually operated surgical instrument to assist with the aspiration of autologous blood or bone marrow and/or placing guidewires (e.g. k-wires) for orthopedic surgery. These guidewires may be used to place other hardware utilized in orthopedic procedures including pedicle screws.

5. **Indications for Use**

The Imbibe Needle is for use in aspirating bone marrow or autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler.

The Imbibe Needle is also for use in the placement of guidewires (e.g. k-wires) during orthopedic surgery.

6. **Performance Data**

Preclinical bench data supplied including mechanical and cadaveric testing demonstrates that the Imbibe Needle is substantially equivalent to the predicate device and any differences do not raise new questions of safety and effectiveness. Further, this testing supports the Imbibe Needle's ability to assist in the placement of guidewires.

7. **Substantial Equivalence**

	Imbibe Needle Predicate Device K050795	**Imbibe Needle New Device TBD**
INDICATIONS FOR USE	The Imbibe Needle is for use in aspirating Bone Marrow or autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler.	The Imbibe Needle is for use in aspirating bone marrow or autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler. The Imbibe Needle is also for use in the placement of guidewires (e.g. k-wires) during orthopedic surgery.
PRODUCT CODE	KNW	KNW, LXH
PRODUCT DESIGN	Handle with cannula, removable	Handle with cannula, removable stylet
STYLET TIP DESIGN	Trocar	Trocar, Beveled
FENESTRATED OFFERING	Yes	Yes
MALE LUER CONNECTION FOR SYRINGE ATTACHMENT	Yes	Yes
STERILIZATION AND SAL	Gamma irradiation, 10^{-6}	Gamma irradiation, 10^{-6}
BIOCOMPATIBILITY	Externally communicating device with tissue/blood/dentin contact for a duration of less than 24 hours	Externally communicating device with tissue/blood/dentin contact for a duration of less than 24 hours

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 1, 2014

Orthovita Incorporated
Mr. John Urtz
Senior Regulatory Affairs Specialist
77 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K140414
Trade/Device Name: Imbibe Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW, LXH
Dated: February 18, 2014
Received: February 18, 2014

Dear Mr. Urtz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K140414

Device Name: Imbibe Needle

Indications for Use:

The Imbibe Needle is for use in aspirating bone marrow or autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler.

The Imbibe Needle is also for use in the placement of guidewires (e.g. k-wires) during orthopedic surgery.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR Over-The Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Felipe Aguel

Date: 2014.04.01 16:08:02 -04'00'